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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ABBOTT LABORATORIES and LABORATOIRES FOURNIER S.A.,	)	
Plaintiffs,	)	C.A. No. 2:09-cv-01007-SDW-MCA
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

LUPIN LIMITED'S AND LUPIN PHARMACEUTICALS, INC.'S
ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin") hereby answer the Complaint of Plaintiffs, Abbott Laboratories ("Abbott") and Laboratoires Fournier S.A., ("Fournier") (collectively "Plaintiffs"), as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 6,277,405 ("the '405 patent"), 7,037,529 ("the '529 patent"), and 7,041,319 ("the '319 patent"). The '405, '529, and '319 patents are collectively referred to herein as the "Patents-in-Suit." This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of Plaintiffs' highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that this is an action for alleged infringement of United States Patent Nos. 6,277,405 ("the '405 patent"); 7,037,529 ("the '529 patent"); and 7,041,319 ("the '319 patent"). Lupin further admits that Lupin Ltd. has filed an ANDA seeking United States Food and Drug Administration ("FDA") approval for Fenofibrate Tablets, 48 mg and 145 mg, prior to the expiration of the '405, '529 and '319 patents. Lupin denies all remaining allegations in Paragraph 1.

THE PARTIES

2. Plaintiff Abbott Laboratories is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies all such allegations.

3. Plaintiff Laboratoires Fournier S.A. is a French corporation having its principal place of business at 28 Boulevard Clemenceau, 21000 Dijon, France.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

4. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals.

ANSWER: Lupin admits that Lupin Ltd. is an Indian corporation having a place of business and registered office located solely in India. Lupin denies all remaining allegations in Paragraph 4.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals in a wholly-owned subsidiary of Lupin Ltd.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI is a Virginia corporation having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Ltd. Lupin denies all remaining allegations in Paragraph 5.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin avers that subject matter jurisdiction is proper only for the claims directed solely against Lupin Ltd. under 35 U.S.C. § 271(e)(2)(A). Lupin denies all remaining allegations in Paragraph 6.

7. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies the allegations in Paragraph 7. Answering

further, to conserve the resources of the parties and the Court, Lupin Ltd. does not contest personal jurisdiction for purposes of this action only.

8. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies the allegations in Paragraph 8. Lupin further avers LPI is not a proper party to this suit. Answering further, to conserve the resources of the parties and the Court, LPI does not contest personal jurisdiction for purposes of this action only.

9. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission to the United States Food and Drug Administration ("FDA") of the ANDA at issue in this case.

ANSWER: Denied.

10. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

ANSWER: Denied.

11. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI is registered to do business in New Jersey. Lupin denies all remaining allegations in Paragraph 11.

12. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey, as its registered agent for the receipt of service of process.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI has appointed National

Registered Agents, Inc. of Princeton, New Jersey, as its registered agent in New Jersey for the receipt of service of process. Lupin denies all remaining allegations in Paragraph 12.

13. Lupin Ltd. and Lupin Pharmaceuticals stipulated in a previous litigation to personal jurisdiction in this Court. *See* Dec. 17, 2006 Stipulation and Order, *Sepracor Inc. v. Sun Pharmaceutical Industries Ltd.*, Case No. 07-4213 (D.N.J.).

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies the allegations in Paragraph 13.

14. Two related lawsuits are currently pending in this Court. On February 29, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the Patents-in-Suit is infringed by Teva's filing of its ANDA No. 90-069. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-1243 (N.D. Ill.). On November 12, 2008, the Illinois court transferred the lawsuit to this Court. On December 3, 2008, this Court acknowledged the transfer. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-5869 (D.N.J.). On November 3, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the Patents-in-Suit is infringed by Biovail's filing of its ANDA No. 90-715. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-CV-6274 (N.D. Ill.). On December 10, 2008, the Illinois court transferred the lawsuit to this Court. On January 5, 2009, this Court acknowledged the transfer. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 09-CV-0005 (D.N.J.).

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14, and therefore denies all such allegations.

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies the allegations in Paragraph 15. Answering further, to conserve the resources of the parties and the Court, Lupin does not contest venue in this district for purposes of this action only.

BACKGROUND

16. Fournier is the owner by assignment of: (a) the '405 patent (attached hereto as Exhibit A); (b) the '529 patent (attached hereto as Exhibit B); and (c) the '319 patent (attached hereto as Exhibit C).

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the cover pages of the '405 patent, the '529 patent and the '319 patent identify "Laboratoires Fournier" as the purported "assignee," and that what purports to be copies of the '405 patent, the '529 patent and the '319 patent were attached to the Complaint as Exhibits A, B and C, respectively. Lupin denies the remaining allegations in Paragraph 16.

17. The '405 and '529 patents are titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It." The '319 patent is titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability."

ANSWER: Lupin admits that the '405 and '529 patents are entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It," and that the '319 patent is entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability." Lupin denies the remaining allegations in Paragraph 17.

18. Abbott is the exclusive licensee of the Patents-in-Suit.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18, and therefore denies all such allegations.

19. The Patents-in-Suit, which currently expire on January 9, 2018, each claim novel fenofibrate compositions that exhibit a particular dissolution profile.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies the allegations in Paragraph 19.

20. Fenofibrate is useful as a lipid and cholesterol lowering agent for treatment of adults with increased triglyceride levels.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore denies all such allegations.

21. Abbott has approval from the FDA to market fenofibrate tablets under the name TRICOR®.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "Abbott" as the "applicant" for an approved New Drug Application ("NDA") for TRICOR® Tablets. Lupin denies all remaining allegations in Paragraph 21.

22. TRICOR® (fenofibrate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under provisions of 21 U.S.C. § 355(j).

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that FDA's Orange Book includes TRICOR®, and that the requirements for an ANDA are set forth in 21 U.S.C. § 355(j) and FDA's corresponding rules and regulations. Lupin denies all remaining allegations in Paragraph 22.

23. The FDA's "Orange Book" also lists patents associated with approved drugs. The Patents-In-Suit are listed in the "Orange Book" in association with TRICOR® (fenofibrate).

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits FDA's Orange Book lists the '405, '529 and '319 patents in connection with TRICOR®. Lupin denies all remaining allegations in Paragraph 23.

24. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 90-856 to the FDA under 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages

("Lupin's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Tablets, 48 mg and 145 mg, if ANDA No. 90-856 is approved by the FDA.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. has submitted an ANDA to FDA for Fenofibrate Tablets, 48 mg and 145 mg. Lupin denies that LPI submitted such an ANDA. Lupin denies all remaining allegations in Paragraph 24.

25. By letter dated January 22, 2009, Lupin advised Abbott and Fournier that it had submitted ANDA No. 90-856 seeking approval to manufacture, use, or sell Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the Patents-in-Suit.

ANSWER: Lupin admits that Lupin Ltd. sent the required notice of its ANDA, dated January 22, 2009 ("Lupin Ltd.'s Notice Letter"), to Plaintiffs, among others. Lupin avers that Lupin Ltd.'s Notice Letter satisfies all statutory and regulatory requirements. Lupin denies all remaining allegations in Paragraph 25.

26. The January 22, 2009 letter also advised Abbott and Fournier that Lupin's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Lupin's opinion, the Patents-in-Suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg.

ANSWER: Lupin admits that Lupin Ltd.'s Notice Letter contains, *inter alia*, the information required by statute and regulation, including notice that Lupin Ltd.'s ANDA contains a so-called "paragraph IV certification" stating that the '405, '529 and '319 patents are invalid, unenforceable and/or not infringed. Lupin denies all remaining allegations in Paragraph 26.

COUNT 1

27. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 26 hereof, as if fully set forth herein.

ANSWER: Lupin repeats, reasserts and incorporates by reference its answers to Paragraphs 1 through 26 above as if fully set forth herein.

28. 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Lupin's submission of an ANDA for approval to sell fenofibrate tablets in 48 mg and 145 mg dosages prior to the expiration of the Patents-in-Suit constitutes an act of infringement of one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). In addition, Lupin's Tablets, 48 mg and 145 mg infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

ANSWER: Denied.

29. On information and belief, Lupin acted without a reasonable basis or a good faith belief that it would not be liable for infringing the Patents-in-Suit.

ANSWER: Denied.

30. Plaintiffs have no adequate remedy at law to redress Lupin's infringement.

ANSWER: Denied.

31. Lupin's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

ANSWER: Denied.

32. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the Patents-in-Suit.

ANSWER: Denied.

* * *

Lupin denies all allegations not expressly admitted herein. Lupin further denies that Plaintiffs are entitled to any of the relief requested, or to any relief whatsoever, and requests that Plaintiffs' Complaint be dismissed with prejudice and that Lupin be awarded their fees and costs incurred defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Lupin asserts the following separate defenses to the Complaint:

First Defense

The manufacture, use, sale, offer for sale, or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '405 patent, the '529 patent or the '319 patent.

Second Defense

The claims of the '405 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Third Defense

The claims of the '529 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Fourth Defense

The claims of the '319 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Fifth Defense

The Court lacks subject matter jurisdiction over any and all claims directed toward LPI.

Sixth Defense

LPI is not a proper party to this suit.

Seventh Defense

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. §§ 271(a), (b), and/or (c).

Eighth Defense

The Complaint fails to state a claim upon which relief can be granted.

Ninth Defense

The Complaint fails to state an exceptional case claim.

Tenth Defense

Any additional defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability.

COUNTERCLAIMS

Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin"), for their Counterclaims against Abbott Laboratories and Laboratoires Fournier S.A., (collectively, "Plaintiffs/Counterclaim-Defendants"), allege as follows:

The Parties

1. Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India.

2. LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202.

3. Abbott Laboratories purports to be a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

4. Laboratoires Fournier S.A. purports to be a French corporation having its principal place of business at 28 Boulevard Clemenceau, 21000 Dijon, France.

Jurisdiction and Venue

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants have purposefully availed themselves of the rights and privileges of this forum by suing Lupin in this District, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

8. Venue for these Counterclaims is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Patents-In-Suit

9. On or about August 21, 2001, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,277,405 B1 ("the '405 patent"), entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It," to André Stamm and Pawan Seth. A true and correct copy of the '405 patent is attached hereto as Exhibit A.

10. On or about April 23, 2002, the PTO issued U.S. Patent No. 6,375,986 B1 ("the '986 patent"), entitled "Solid Dose Nanoparticulate Compositions Comprising a Synergistic

Combination of a Polymeric Surface Stabilizer and Dioctyl Sodium Sulfosuccinate," to Niels P. Ryde and Stephen B. Ruddy. A true and correct copy of the '986 patent is attached hereto as Exhibit B.

11. On or about November 25, 2003, the PTO issued U.S. Patent No. 6,652,881 B2 ("the '881 patent"), entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability," to André Stamm and Pawan Seth. A true and correct copy of the '881 patent is attached hereto as Exhibit C.

12. On or about May 2, 2006, the PTO issued U.S. Patent No. 7,037,529 B2 ("the '529 patent"), entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It," to André Stamm and Pawan Seth. A true and correct copy of the '529 patent is attached hereto as Exhibit D.

13. On or about May 9, 2006, the PTO issued U.S. Patent No. 7,041,319 B2 ("the '319 patent"), entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability," to André Stamm and Pawan Seth. A true and correct copy of the '319 patent is attached hereto as Exhibit E.

14. On or about October 2, 2007, the PTO issued U.S. Patent No. 7,276,249 B2 ("the '249 patent"), entitled "Nanoparticulate Fibrate Formulations," to Tuula Ryde, Evan E. Gustow, Stephen B. Ruddy, Rajeev Jain, Rakesh Patel and Michael John Wilkins. A true and correct copy of the '249 patent is attached hereto as Exhibit F.

15. On or about January 22, 2008, the PTO issued U.S. Patent No. 7,320,802 B2 ("the '802 patent"), entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," to Tuula Ryde, Evan E. Gustow, Stephen B. Ruddy, Rajeev Jain, Rakesh Patel

and Michael John Wilkins. A true and correct copy of the '802 patent is attached hereto as Exhibit G.

16. Abbott has submitted information on the '405 patent, the '986 patent, the '881 patent, the '529 patent, the '319 patent, the '249 patent and the '802 patent to FDA for listing in the Orange Book in connection with TRICOR®, thus alleging and asserting that such patents "claim[] the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

17. On information and belief, Abbott purports and/or claims to be the exclusive licensee of, and/or to have the right to enforce, the '405 patent, the '986 patent, the '881 patent, the '529 patent, the '319 patent, the '249 patent and the '802 patent.

18. On information and belief, Plaintiffs/Counterclaim-Defendants purport and/or claim to own and/or license, and/or to have the right to enforce, the '405 patent, the '986 patent, the '881 patent, the '529 patent, the '319 patent, the '249 patent and the '802 patent.

19. On or about March 6, 2009, Plaintiffs/Counterclaim-Defendants filed suit against Lupin in this District alleging infringement of the '405 patent, the '529 patent and the '319 patent.

COUNT I
(Declaration of Non-Infringement of the '405 Patent)

20. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-19.

21. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '405 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

22. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '405 patent.

23. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '405 patent.

COUNT II
(Declaration of Invalidity of the '405 Patent)

24. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-23.

25. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '405 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

26. The claims of the '405 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

27. Lupin is entitled to a declaration that the claims of the '405 patent are invalid.

COUNT III
(Declaration of Non-Infringement of the '986 Patent)

28. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-27.

29. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '986 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

30. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '986 patent.

31. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '986 patent.

COUNT IV
(Declaration of Invalidity of the '986 Patent)

32. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-31.

33. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '986 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

34. The claims of the '986 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

35. Lupin is entitled to a declaration that the claims of the '986 patent are invalid.

COUNT V
(Declaration of Non-Infringement of the '881 Patent)

36. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-35.

37. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '881 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

38. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '881 patent.

39. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '881 patent.

COUNT VI
(Declaration of Invalidity of the '881 Patent)

40. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-39.

41. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '881 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

42. The claims of the '881 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

43. Lupin is entitled to a declaration that the claims of the '881 patent are invalid.

COUNT VII
(Declaration of Non-Infringement of the '529 Patent)

44. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-43.

45. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '529 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

46. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '529 patent.

47. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '529 patent.

COUNT VIII
(Declaration of Invalidity of the '529 Patent)

48. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-47.

49. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '529 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

50. The claims of the '529 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

51. Lupin is entitled to a declaration that the claims of the '529 patent are invalid.

COUNT IX
(Declaration of Non-Infringement of the '319 Patent)

52. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-51.

53. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '319 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

54. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '319 patent.

55. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '319 patent.

COUNT X
(Declaration of Invalidity of the '319 Patent)

56. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-55.

57. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '319 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

58. The claims of the '319 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

59. Lupin is entitled to a declaration that the claims of the '319 patent are invalid.

COUNT XI
(Declaration of Non-Infringement of the '249 Patent)

60. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-59.

61. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '249 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

62. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '249 patent.

63. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '249 patent.

COUNT XII
(Declaration of Invalidity of the '249 Patent)

64. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-63.

65. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '249 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

66. The claims of the '249 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

67. Lupin is entitled to a declaration that the claims of the '249 patent are invalid.

COUNT XIII
(Declaration of Non-Infringement of the '802 Patent)

68. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-67.

69. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-

infringement of the '802 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

70. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '802 patent.

71. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '802 patent.

COUNT XIV
(Declaration of Invalidity of the '802 Patent)

72. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-71.

73. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '802 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

74. The claims of the '802 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

75. Lupin is entitled to a declaration that the claims of the '802 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Abbott Laboratories and Laboratoires Fournier S.A. as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '405 patent;

(b) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '986 patent;

(c) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '881 patent;

(d) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '529 patent;

(e) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '319 patent;

(f) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not

infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '249 patent;

(g) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '802 patent;

(h) Declaring that the claims of the '405 patent are invalid;

(i) Declaring that the claims of the '986 patent are invalid;

(j) Declaring that the claims of the '881 patent are invalid;

(k) Declaring that the claims of the '529 patent are invalid;

(l) Declaring that the claims of the '319 patent are invalid;

(m) Declaring that the claims of the '249 patent are invalid;

(n) Declaring that the claims of the '802 patent are invalid;

(o) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Lupin its attorneys' fees, costs, and expenses in this action; and

(p) Awarding Lupin any further and additional relief as the Court deems just and proper.

Jury Demand

Lupin demands a trial by jury on all issues so triable.

Dated: May 8, 2009.

Respectfully submitted,

SAIBER LLC
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Lupin Limited and Lupin Pharmaceuticals, Inc.

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Lupin hereby certifies that the United States Patent Nos. 7,276,249, 7,320,802 and 6,375,986 are also the subject of litigation in *Elan Pharma International Ltd. et al. v. Lupin Limited et al.*, Civil Action No. 2:09-cv-01008-JAG-MCA (D.N.J.)

Dated: May 8, 2009

s/Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Lupin hereby certifies that Lupin seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: May 8, 2009

s/Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)